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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

Our reference: 2918667

June 24, 1998

Ira L. Goldberg
Chief Executive Officer
Threshold Enterprises, Ltd.
23 Janis Way
Scotts Valley, CA 95066

Dear Mr. Goldberg:

This letter is written in reference to your firm's marketing and distribution of Source Naturals® Diet-Phen Tablets, Source Naturals® Ephedra-Free Diet-Phen Tablets, Horizon® Nutraceuticals Slim-Phen Tablets, and Horizon® Nutraceuticals Ephedra-Free Slim-Phen Tablets. A review of the labels for your products, suggest that these products are alternatives to the prescription drug, Phentermine. This prescription drug is intended to treat obesity. Labeling your products as alternatives to Phentermine represents claims that your products are intended for the same use as Phentermine. Thus, you are representing your products as treatments for obesity.

Therefore these products are drugs as defined in Section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). They are also "new drugs" [Section 201(p)] due to a lack of any evidence that these products are approved for or generally recognized as safe and effective for the treatment of obesity.

Since these drugs are "new drugs," they may not be legally marketed in the United States without approved new drug applications (Section 505 (a) of the Act).

These drugs are also misbranded because their labeling fails to bear adequate directions for use (Section 502(f)(1) of the Act) and their labeling is false and misleading since it suggests that the products are recognized as safe and effective for their intended use (Section 502(a) of the Act) when this has not been established.

This letter is not intended to be an all inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the Food and Drug Administration, San Francisco District Office, attention: Paul A. Peterson, Investigator, Drug/Bioresearch Monitoring Team.

Sincerely,

Charles D Moss
Acting District Director

for Patricia C. Ziobro
District Director
San Francisco District